

REMARKS

All previously pending claims 1-3, 5-9 and 11 have been canceled herewith without prejudice. New claims 13-20 have been added herewith, which newly added claims seek to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Moreover, the newly added claims find adequate support from the specification of the application, as filed. Accordingly, applicants respectfully submit that (i) no new matter has been introduced, and (ii) the Examiner's claim rejections, based on Section 112, first and second paragraphs, Section 102 based on Ohashi et al., and Section 103(a) based on a combination of Ohashi et al. and Grant et al., have been overcome and should be withdrawn.

Applicants would also like to thank Examiner Oh for the courtesy he extended to applicants' counsel during a personal interview on August 30, 2005 and, again, on October 25, 2005, together with Examiner Cecilia Tsang. During those interviews, applicants' counsel discussed the contents of a poster presentation, which showed some of the physical and spectral properties of the isolated orthorhombic crystalline substance that is claimed in the pending application. Also discussed were the corresponding physical and spectral properties of tablets prepared from the isolated orthorhombic crystalline substance, which showed that the orthorhombic crystalline nature of the substance is preserved during the tablet manufacturing process. Thus, applicants respectfully assert that the benefits of greater solubility (e.g., greater bioavailability) of the orthorhombic crystalline form carry over to the finished product, in the present case, tablets and capsules. A copy of this poster presentation is being submitted herewith as an Appendix to a Rule 132 Declaration by Dr. Kenneth W. Locke.

Applicants counsel, during the interview of October 25, 2005, also brought samples of monoclinic crystalline substance (granular crystals, which do not cling to glass walls of vial) and samples of orthorhombic crystalline substance (finer, more powdery crystals, which cling to the glass walls of vial). Applicants' counsel exclaimed that monoclinic crystals appear to be the thermodynamically preferred crystalline form of the substance in question judging from the results of differential scanning calorimetry experiments. See, Appendix to Rule 132 Declaration and paragraph 6 of that Declaration. It would also appear that the monoclinic, thermodynamically preferred crystalline form is the crystalline form obtained by following the teachings of Ohashi et al., which make no extraordinary provisions for crystallization or purification, which might favor a less thermodynamically preferred crystalline form. See, for

example, Ohashi *et al.*, col. 6, lines 42-44 ("This crystal was recrystallized from ethanol to [give] colorless crystals, . . ."), or col. 14, lines 40-43 ("The resultant residue was separated and purified through silica-gel column chromatography (eluting with ethanol:methylene chloride = 3:100) to give the title compound . . .").

Accordingly, claims directed to pharmaceutical compositions, isolated orthorhombic crystalline substance and methods of treatment claims are presented herein for the Examiner's consideration.

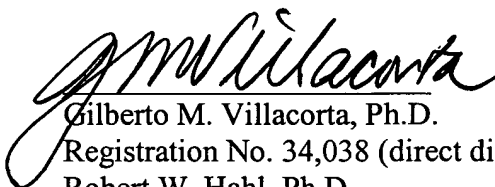
CONCLUSION

Claims 13-20 are pending in the application. Applicants' respectfully submit that the pending claims recite subject matter that is patentable and meets statutory requirements. A notice of allowance is cordially solicited.

AUTHORIZATION

Applicants believe there are no fees required for this filing. However, to the extent required, the Commissioner is hereby authorized to charge any additional fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,
KATTEN MUCHIN ROSENMAN LLP



Gilberto M. Villacorta, Ph.D.
Registration No. 34,038 (direct dial: 202 625 3838)
Robert W. Hahl, Ph.D.
Registration No. 33,893

Dated: November 10, 2005

Patent Administrator
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061